

Memorandum

Date: May 23, 2019

To: Marla Swain, Ph.D., Consumer Safety Officer, Division of Food Contact Substances, HFS-275

Through: Leah D. Proffitt, Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

From: Biologist, Environmental Team, Division of Science and Technology, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 1960 (an aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722 -84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) and/or dipicolinic acid (DPA) (CAS Reg. No. 499-83-2))

Notifier: Harcros Chemicals, Inc.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1960, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

The Food Contact Substance (FCS) that is the subject of FCN 1960 is an aqueous mixture of PAA, HP, acetic acid, HEDP, and optionally sulfuric acid and/or DPA. The FCS is intended for use as an antimicrobial agent in process water, ice, and brine used in the production and preparation of meat, poultry, processed and pre-formed meat and poultry products, fish, seafood, fruits, vegetables, seeds, nuts, and shell eggs; and in sauces and marinades used in the production and preparation of poultry and processed and pre-formed meat and poultry products.

After this notification becomes effective, copies of this FONSI, revision sheet and the notifier's environmental assessment, dated March 7, 2019, may be made available to the public. We will post digital transcriptions of the FONSI, revision sheet and the environmental assessment on the agency's public website.

Please let us know if there is any change in the identity or use of the food contact substance.

Sarah C. Winfield

Attachments:

Finding of No Significant Impact

Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1960, submitted by Harcros Chemicals, Inc. for the use of an aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) and/or dipicolinic acid (DPA) (CAS Reg. No. 499-83-2) as an antimicrobial agent in process water, ice, and brine used in the production and preparation of meat, poultry, processed and pre-formed meat and poultry products, fish, seafood, fruits, vegetables, seeds, nuts, and shell eggs; and in sauces and marinades used in the production and preparation of poultry and processed and pre-formed meat and poultry products. The components of the FCS mixture will not exceed:

1. 2000 ppm PAA, 947 ppm HP, 116 ppm HEDP and 0.5 ppm DPA in process water and ice used to spray, wash, rinse, or dip meat carcasses, parts, trim, and organs and in chiller water or scald water for meat carcasses, parts, trim, and organs; and
2. 2000 ppm PAA, 947 ppm HP, 116 ppm HEDP, and 0.5 ppm DPA in process water and ice used to spray, wash, rinse or dip poultry carcasses, parts, trim, and organs and in chiller water, immersion baths (e.g., less than 40 °F), or scald water for poultry carcasses, parts, trim, and organs; and
3. 495 ppm PAA, 234 ppm HP, 29 ppm HEDP, and 0.1 ppm DPA in water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed meat products; and
4. 230 ppm PAA, 109 ppm HP, 13 ppm HEDP, and 0.1 ppm DPA in water, brine, and ice for washing, rinsing, or cooling of processed and pre-formed poultry products; and
5. 230 ppm PAA, 109 ppm HP, and 13 ppm HEDP in process water and ice used to commercially prepare fish and seafood; and
6. 350 ppm PAA, 166 ppm HP, 20 ppm HEDP, and 0.1 ppm DPA in process water and ice used for washing or chilling fruits and vegetables in a food processing facility; and
7. 229 ppm PAA, 108 ppm HP, and 13 ppm HEDP in process water used as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia) as a well as edible seeds (chia, flax, and hemp) and nuts (almond, cashew, and walnut). The FCS will be applied in the preparing, packing, or holding of the food for commercial purposes, consistent with the FD&C Act section 201(q)(1)(B)(i). The treated edible seeds can be consumed directly or further processed into flour, protein, or oil. The treated edible nuts are intended to be consumed as nuts. The treated seeds for sprouting are intended to be consumed as sprouts.; and
8. 2000 ppm PAA, 947 ppm HP, and 116 ppm HEDP in water for washing shell eggs; and
9. 50 ppm PAA, 24 ppm HP, and 3 ppm HEDP in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts and pieces; and surface sauces and marinades applied on processed and pre-formed meat and poultry products.

The Office of Food Additive Safety has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated March 7, 2019. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below.

Manufacture of the FCS is not expected to result in environmental introduction, nor adverse environmental impact. When the FCS is used as an antimicrobial in process water, ice, and brine used in the production and preparation of meat, poultry, processed and pre-formed meat and poultry products, fish, seafood, fruits, vegetables, seeds, nuts, and shell eggs; and in sauces and marinades used in the production and preparation of poultry and processed and pre-formed meat and poultry products, environmental introduction could occur via wastewater. When used on fish and seafood in a fishing vessel, wastewater will be discharged into the ocean, resulting in considerable dilution and therefore

negligible introduction of the FCS into the environment. For all other uses, we expect wastewater from an on-site wastewater treatment facility to discharge to a Publicly Owned Treatment Works (POTW) or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters. For FCS that reaches a POTW, land application of sewage treatment sludge could result in terrestrial introduction of the FCS.

Complete degradation of the FCS components (except HEDP and DPA) is expected to occur during use, discharge into the ocean and/or treatment at the on-site wastewater treatment plant or POTW. Specifically, peroxyacetic acid will breakdown into oxygen, water and acetic acid, while hydrogen peroxide will break down into oxygen and water. Acetic acid is expected to dissociate in wastewater and degrade in the ocean or at the wastewater treatment facility/POTW. Sulfuric acid will completely dissociate into sulfate ions and hydrated protons, neither of which are a toxicological or environmental concern at the proposed use levels. As such, the environmental impacts of these FCS components are not considered in further detail in the EA. The EA focuses on the environmental fate and effects of HEDP and DPA.

The EA lays out the worst-case scenario and assumes the highest use rate of the FCS goes directly into wastewater. For these uses, the highest use concentrations of HEDP and DPA are 116 and 0.5 ppm, respectively, and these are assumed equal to the maximum concentration of HEDP and DPA in wastewater. Environmental Introduction Concentrations (EICs) for HEDP were calculated assuming 80 percent of the HEDP partitions to sludge during on-site wastewater treatment (and 20 percent of the HEDP remains in the water). Expected Environmental Concentrations (EECs) of HEDP were calculated assuming a ten-fold dilution when the disposed wastewater mixes with surface waters. Therefore, the terrestrial EEC for HEDP is 93 ppm ($116 \text{ ppm} * 0.80$) and the aquatic EEC for HEDP is 2.3 ppm ($[116 \text{ ppm} * 0.20] / 10$). DPA is expected to remain in the aqueous compartment of wastewater, and therefore an aquatic EEC for DPA was calculated assuming a ten-fold dilution when the disposed wastewater mixes with surface waters. The aquatic EEC for DPA is 0.05 ppm (0.5 ppm / 10).

Terrestrial toxicity studies with HEDP demonstrated no effects on earthworms at levels up to 1,000 ppm soil dry weight and the 14-day LC50 for birds was determined to be greater than 284 mg/kg body weight. The terrestrial HEDP EEC is 93 ppm, a worst-case concentration that assumes no dilution from mixing nor degradation of HEDP and is over two-fold lower than terrestrial toxicity study endpoints, therefore, there is no toxicity expected from land application of sludge that contains HEDP from the proposed use of the FCS. In evaluation of the aquatic toxicity of the FCS, the lowest relevant HEDP concentration for aquatic toxicity was determined to be the 28 day No Observed Effect Concentration (NOEC) of 10 ppm for *Daphnia magna*. The calculated aquatic HEDP EEC of 2.3 ppm is a conservative estimate, as it assumes the concentration of HEDP in wastewater is the same as the at-use concentration. The aquatic HEDP EEC of 2.3 ppm is about four-fold lower than the 10 ppm NOEC for *Daphnia magna*. The aquatic DPA EEC of 0.05 ppm is over 100-fold lower than the range of reported and predicted aquatic endpoints for DPA (ranging from 7.69 to 324 mg/L, including chronic and acute, as well as plant and animal endpoints). Therefore, the proposed use of the FCS is not expected to have an adverse effect on aquatic organisms.

We do not expect a net increase in the use of energy and resources from the use of the FCS, nor do we expect adverse environmental effects, which would necessitate alternative actions to those proposed in this FCN. The alternative of not approving the action proposed herein would result in the continued use of materials which the FCS would otherwise replace (*i.e.*, similar antimicrobial agents already on the market); such action would have no significant environmental impact. Furthermore, as the use and disposal of the FCS is not expected to result in significant adverse environmental impacts, mitigation measures are not identified.

The use of the FCS, as described in FCN 1960, as an antimicrobial in in process water, ice, and brine used in the production and preparation of meat, poultry, processed and pre-formed meat and poultry products, fish, seafood, fruits, vegetables, seeds, nuts, and shell eggs; and in sauces and marinades used in the production and preparation of poultry

and processed and pre-formed meat and poultry products, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: see electronic signature

Sarah C. Winfield

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Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

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Approved by _____ Date: see electronic signature

Leah D. Proffitt

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U.S. Food and Drug Administration

Revision Sheet for the March 7, 2019 EA for FCN 1960

Dated: May 23, 2019

The U.S. Food and Drug Administration (FDA) in its review of the March 7, 2019 Environmental Assessment (EA) for Food Contact Substance Notification (FCN) 1960 concluded that the action will not constitute a significant impact. The revision is issued to make a minor change and update of an editorial nature that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to clarify the following:

On page 4, the EA states:

"Sulfuric acid dissociates readily in water to sulfate ions (SO₄-2) and hydrated protons; at environmentally-relevant concentrations, sulfuric acid is practically totally dissociated (OECD SIDS, 2001)."

However, the reference (OECD SIDS, 2001) is never fully provided in a footnote or the reference section. Therefore, we are providing the full reference here:

The Organization for Economic Cooperation and Development (OECD) SIDS Voluntary Testing Programme for International High Production Volume Chemicals (OECD SIDS), Sulfuric Acid, 2001; available at:

<https://hpvchemicals.oecd.org/UI/handler.axd?id=248f397d-64b3-4e14-8be9-473974e8dfdb>.